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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 09/628,361  
Filing Date: July 18, 2000  
Applicant(s): Balasubramaniam et al.  
Title: **Compounds for Control of Appetite, Blood Pressure, Cardiovascular Response, Libido, and Circadian Rhythm**  
Group Art Unit: Unknown  
Examiner: Unknown  
Atty Docket No.: UOC-136R

Cincinnati, Ohio 45202

February 16, 2001

Assistant Commissioner for Patents  
Washington, DC 20231

## **INFORMATION DISCLOSURE STATEMENT** **FILED PURSUANT TO 37 CFR §§ 1.56 AND 1.97-1.98**

Sir:

In accordance with the duty of candor and good faith imposed by 37 C.F.R. §1.56, and the means of complying with that duty according to 37 C.F.R. §§1.97 and 1.98, the Applicants call the references listed on the attached PTO-1449 form to the attention of the United States Patent and Trademark Office in connection with the above-identified patent application. The Applicants have enclosed a copy of the cited

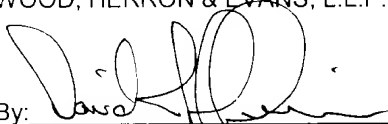
- references and request that the Examiner consider the cited references and make an independent evaluation of their materiality.

It is believed that a first Office Action has not yet been issued.

Accordingly, the Applicants do not believe that any fees are due in connection with this submission. However, if such fees are necessary, the Commissioner is authorized to charge any necessary fees to deposit account 23-3000.

Respectfully submitted,

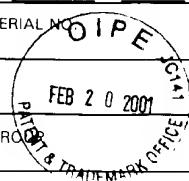
WOOD, HERRON & EVANS, L.L.P.

By: 

David E. Jefferies, Reg. No. 46,800

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SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. UOC/136R	SERIAL NO.
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	M.L						
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)	
M.R	Anita Westlind-Danielson et al., <u>Neuropeptide Y receptors and the inhibition of adenylate cyclase in the human frontal and temporal cortex</u> , Neuroscience Letters, Vol. 74, 1987, pp. 237-242.
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M.T	

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L.R.	Anders Uden et al., <u>Neuropeptide Y receptor in the rat brain</u> , Eur. J. Biochem., Vol. 145, 1984, pp. 525-530.
L.S.	Claes Wahlestedt et al., <u>Evidence for different pre- and post-junctional receptors for neuropeptide Y and related peptides</u> , Regulatory Peptides, Vol. 13, 1986, pp. 307-318.
L.T.	Mary W. Walker et al., <sup>125</sup> I-Neuropeptide Y and <sup>125</sup> I-Peptide YY Bind to Multiple Receptor Sites in Rat Brain, Molecular Pharmacology, Vol. 34, Sept. 8, 1988, pp. 779-792.

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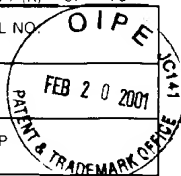
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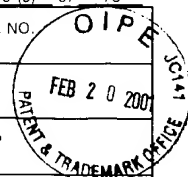
	R	Soren P. Sheikh et al., <u>Y<sub>2</sub>-type receptors for peptide YY on renal proximal tubular cells in the rabbit</u> , Am. J. Physiol., Vol. 26, 1989, pp. F978-F984.
	S	Soren P. Sheikh et al., <u>Structural Characterization of Y<sub>1</sub> and Y<sub>2</sub> Receptors for Neuropeptide Y and Peptide YY by Affinity Cross-linking</u> , J. Biol. Chem, Vol. 265, No. 14, May 15, 1990, pp. 8304-8310.
	T	R.T. Shuman et al., <u>Structure-Activity Studies of Enkephalin Tetrapeptides</u> , in <u>Peptides: Proceedings of the 2<sup>nd</sup> American Peptide Symposium</u> , Rockford, IL, 1981, pp. 617-621.

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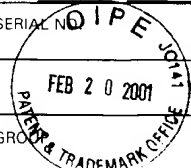
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OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)	
J.R	Eberhard Schroder et al., <u>The Peptides, Vol. 1, Methods of Peptide Synthesis</u> , Academic Press, 1965, pp. 72-75.
J.S	Thue W. Schwartz et al., <u>Signal Epitopes in the Three-Dimensional Structure of Neuropeptide Y: Interaction with Y<sub>1</sub>, Y<sub>2</sub>, and Pancreatic Polypeptide Receptors</u> , in <u>Central and Peripheral Significance of Neuropeptide Y and its Related Peptides</u> , (Janet M. Allen et al., eds.), Annals of New York Academy of Sciences, Vol. 611, 1990, pp. 35-47.
J.T	Soren P. Sheikh et al., <u>Localization of Y<sub>1</sub> receptors for NPY and PYY on vascular smooth muscle cells in rat pancreas</u> , Am. J. Physiol., Vol. 260, 1991, pp. G250-G257.
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## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

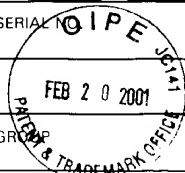
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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

I.R	B. Penke et al., <u>New Synthetic Approach to Peptide Sulfate Esters. Synthesis and Biological Activities of CCK Analogs</u> , Synthesis of Peptides: Methods, Proceedings of the 8 <sup>th</sup> American Peptide Symposium, Rockford, IL, 1983, pp. 119-122.
I.S	Marc Rodriguez et al., <u>Synthesis and Biological Activities of Pseudopeptide Analogues of the C-Terminal Heptapeptide of Cholecystokinin</u> , On the Importance of the Peptide Bonds, J. Med. Chem., Vol. 30, 1987, pp. 1366-1373.
I.T	Y. Sasaki et al., <u>Solid Phase Synthesis of Peptides Containing the CH<sub>2</sub>NH Peptide Bond Isostere</u> , Peptides, Vol. 8, 1987, pp. 119-121.

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H.R	Shin-ichi Mihara et al., <u>Neuropeptide Y-induced intracellular Ca<sup>2+</sup> increases in vascular smooth muscle cells</u> , FEBS Letters, Vol. 259, No. 1, Dec. 1989, pp. 79-82.
H.S	Harvey J. Motulsky et al., <u>Neuropeptide Y Mobilizes Ca<sup>2+</sup> and inhibits adenylyate cyclase in human erythroleukemia cells</u> , Amer. J. of Physiol., 1988, pp. E880-E885.
H.T	William M. Pardridge et al., <u>Endorphin Chimeric Peptides: Transport through the Blood-Brain Barrier in Vivo and Cleavage of Disulfide Linkage by Brain</u> , Endocrinology, Vol. 126, No. 2, 1990, pp. 977-984.

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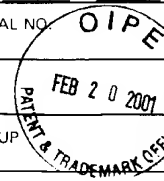
  

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	G.R	Jan M. Lundberg et al., <u>Neuropeptide Y receptor in pig spleen: binding characteristics, reduction of cyclic AMP formation and calcium antagonist inhibition of vasoconstriction</u> , European Journal of Pharmacology, Vol. 145, 1988, pp. 21-29.					
	G.S	R.B. Merrifield, <u>Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide</u> , J. Amer. Chem. Soc., Vol. 85, July 20, 1963, pp. 2149-2154.					
	G.T	Martin C. Michel, <u>Receptors for neuropeptide Y: multiple subtypes and multiple second messengers</u> , TIPS, Vol. 12, Oct. 1991, pp. 389-394.					
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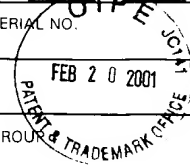
  

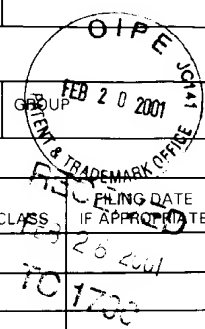
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)	
F.R	Eric A. Gordon et al., <u>Characterization of Functional Neuropeptide Y Receptors in a Human Neuroblastoma Cell Line</u> , Journal of Neurochemistry, International Society for Neurochemistry, 1990, pp. 506-513.
F.S	M. Heilig et al., <u>Neuropeptide Y: an overview of central distribution, functional aspects, and possible involvement in neuropsychiatric illnesses</u> , Dept. of Psychiatry and Neurochemistry, University of Lund, Lund, Sweden, Mar. 17, 1990, pp. 95-114.
F.T	Joseph Hinson et al., <u>Neuropeptide Y stimulates inositol phospholipid hydrolysis in rat brain miniprisms</u> , Brain Research, Vol. 446, 1988, pp. 379-382.
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	E.R.	Roger M. Freidinger et al., <u>Synthesis of 9-Fluorenylmethoxycarbonyl-Protected N-Alkyl Amino Acids by Reduction of Oxazolidinones</u> , J. Org. Chem., Vol. 48, 1983, pp. 77-81.					
	E.S.	Jannie Fuhlendorff et al., [ <u>Leu<sup>31</sup></u> , <u>Pro<sup>34</sup></u> ] Neuropeptide Y: A specific Y <sub>1</sub> receptor agonist, Proc. Natl. Acad. Sci., Vol. 87, Jan. 1990, pp. 182-186.					
	E.T.	Glover et al., <u>Conformational studies on the pancreatic polypeptide hormone family</u> , Eur. J. Biochem. Vol. 142, 1985, pp. 379-385.					
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	D.S	Jean-Alain Fehrentz et al., <u>An Efficient Synthesis of Optically Active <math>\alpha</math>-(<i>r</i>-Butoxycarbonylamino)-aldehydes from <math>\alpha</math>-Amino Acids</u> , Communications, August, 1983, pp. 676-678.					
	D.T	James F. Flood et al., <u>Dissociation of the Effects of Neuropeptide Y on Feeding and Memory: Evidence for Pre- and Postsynaptic Mediation</u> , Peptides, Vol. 10, 1989, pp. 963-966.					
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
C.R	S.T. Cheung et al., <u>N-Methylamino acids in peptide synthesis. V. The synthesis of N-tert-butyloxycarbonyl, N-methylamino acids by N-methylation</u> , Can. J. Chem., Vol. 55, 1997, pp. 906-910.						
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C.T	David H. Coy et al., <u>Solid Phase Reductive Alkylation Techniques in Analogue Peptide Bond and Side-Chain Modification</u> , Tetrahedron, Vol. 44, No. 3, 1988, pp. 835-841.						
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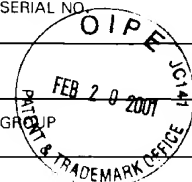
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B.A	5	3	2	8	8	9	9	7/1994	Boublik et al.			
	B.B												
	B.C												
	B.D												
	B.E												
	B.F												
	B.G												
	B.H												
	B.I												
	B.J												
	B.K												

## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	B.L						
	B.M						
	B.N						
	B.O						
	B.P						
	B.Q						

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

B.R	Ulrich Bickel et al., <u>Synthesis and Bioactivity of Monobiotinylated DALDA: A <math>\mu</math>-Specific Opioid Peptide Designed for Targeted Brain Delivery</u> , Journal of Pharmacology and Experimental Therapeutics, Vol. 268, No. 2, 1994, pp. 791-796.
B.S	D. Bleakman et al., <u>Neuropeptide Y inhibits <math>Ca^{2+}</math> influx into cultured dorsal root ganglion neurones of the rat via a <math>Y_2</math> receptor</u> , Dept. of Pharmacological and Physiological Sciences, University of Chicago, Mar. 11, 1991, pp. 1781-1789.
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A.A	3 8 4 2 0 6 7	10/1974	Dimitrios Sarantakis			
	A.B	3 8 6 2 9 2 5	1/1975	Sarantakis et al.			
	A.C	3 9 7 2 8 5 9	8/1976	Fujino et al.			
	A.D	4 1 0 5 6 0 3	8/1978	Vale, Jr. et al.			
	A.E	4 2 4 4 9 4 6	1/1981	Rivier et al.			
	A.F	4 2 9 7 3 4 6	10/1981	Rips et al.			
	A.G	4 4 1 5 5 5 8	11/1983	Vale, Jr. et al.			
	A.H	4 4 0 0 3 6 4	12/1984	Rivier et al.			
	A.I	4 8 3 0 3 4 3	6/1989	Waeber et al.			
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	A.K	5 2 7 0 3 0 2	12/1993	Shiosaki et al.			

## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
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	A.M					
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A.R	A. Balasubramaniam et al., <u>Characterization of Neuropeptide Y Binding Sites in Rat Cardiac Ventricular Membranes</u> , Peptides, Vol. 11, 1990, pp. 545-550.
A.S	A. Balasubramaniam et al., <u>Synthesis and biological properties of 4-norleucine-neuropeptide Y; secondary structure of neuropeptide Y</u> , Biochimica et Biophysica Acta, Vol. 997, 1989, pp. 176-181.
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